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AP3 Rec'd PCT/PTO 15 JUN 2008

INFORMATION DISCLOSURE  
STATEMENT  
Patent Application  
Docket No. ARS-129

June 15, 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Yolande Rouiller  
Docket No. : ARS-129  
For : Process for the Production of Tumor Necrosis Factor-Binding Proteins

Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §§1.97 AND 1.98

Sir:

In accordance with 37 CFR §1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. A copy of each cited reference is enclosed. However, Applicant has not submitted a copy of the U.S. patent cited on attached Form PTO/SB/08 pursuant to 37 CFR 1.98(a)(2)(ii).

It is respectfully requested that the references cited on the attached form PTO/SB/08 be considered in the examination of the subject application and that their consideration be made of record.

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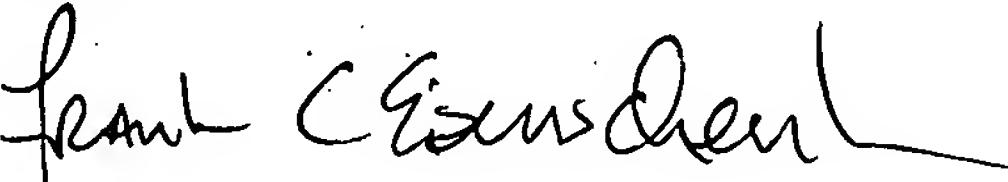
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Docket No. ARS-129  
Patent Application

Applicant respectfully asserts that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statements.

Respectfully submitted,



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FCE/sl

Attachments: Form PTO/SB/08; copies of references cited therein

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PTO/SB/08A (08-03)

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Substitute for form 1449A/PTO				<i>Complete if Known</i>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				<b>Application Number</b>	
				<b>Filing Date</b>	June 15, 2006
				<b>First Named Inventor</b>	Yolande Rouiller
				<b>Art Unit</b>	
				<b>Examiner Name</b>	
<b>Sheet</b>	1	<b>of</b>	4	<b>Attorney Docket Number</b>	ARS-129

## **U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	U1	US-5,705,364	01-06-1998	ETCHEVERRY et al.	All
	U2	US-			
	U3	US-			
	U4	US-			
	U5	US-			
	U6	US-			
	U7	US-			
	U8	US-			

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	F1	WO 00/36092	06-22-2000	BIOGEN, INC.	All	
	F2	WO 00/54651 (CD-ROM)	09-21-2000	HUMAN GENOME SCIENCES, INC.	All	
	F3	WO 03/046160	06-05-2003	APPLIED RESEARCH SYSTEMS ARS HOLDING N.V.	All	
	F4	WO 03/083066	10-09-2003	IMMUNEX CORPORATION	All	
	F5	WO 2004/058800 (CD-ROM)	07-15-2004	BRISTOL-MYERS SQUIBB COMPANY	All	
	F6					
	F7					

Examiner Signature		Date Considered
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Sheet

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Application Number	
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Group Art Unit	
Examiner Name	

Attorney Docket Number ARS-129

**NON PATENT LITERATURE DOCUMENTS**

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	R1	ALTSCHUL, S.F. et al. "Basic Local Alignment Search Tool", <i>J. Mol. Biol.</i> , 1990, pp. 403-410, Vol. 215.	
	R2	ALTSCHUL, S.F. et al. "Gapped BLAST and PSI-BLAST: a new generation of protein database search programs", <i>Nucleic Acids Research</i> , 1997, pp. 3389-3402, Vol. 25, No. 17.	
	R3	ANDERSEN, D.C. et al. "Multiple Cell Culture Factors Can Affect the Glycosylation of Asn-184 in CHO-Produced Tissue-Type Plasminogen Activator", <i>Biotechnology and Bioengineering</i> , October 5, 2000, pp. 25-31, Vol. 70, No. 1.	
	R4	BARNABÉ, N. et al. "Effect of Temperature on Nucleotide Pools and Monoclonal Antibody Production in a Mouse Hybridoma", <i>Biotechnology and Bioengineering</i> , November 20, 1994, pp. 1235-1245, Vol. 44, No. 10.	
	R5	BORYS, M.C. et al. "Culture pH Affects Expression Rates and Glycosylation of Recombinant Mouse Placental Lactogen Proteins by Chinese Hamster Ovary (CHO) Cells", <i>Bio/Technology</i> , June 1993, pp. 720-724, Vol. 11.	
	R6	CASTRO, P.M.L. et al. "The Macroheterogeneity of Recombinant Human Interferon-γ Produced by Chinese-hamster Ovary Cells is Affected by the Protein and Lipid Content of the Culture Medium", <i>Biotechnol. Appl. Biochem.</i> , 1995, pp. 87-100, Vol. 21.	
	R7	CHUPPA, S. et al. "Fermentor Temperature as a Tool for Control of High-Density Perfusion Cultures of Mammalian Cells", <i>Biotechnology and Bioengineering</i> , July 20, 1997, pp. 328-338, Vol. 55, No. 2.	
	R8	DEVEREUX, J. et al. "A Comprehensive Set of Sequence Analysis Programs for the VAX", <i>Nucleic Acids Research</i> , 1984, pp. 387-395, Vol. 12, No. 1.	
	R9	DUCOMMUN, P. et al. "Monitoring of Temperature Effects on Animal Cell Metabolism in a Packed Bed Process", <i>Biotechnology and Bioengineering</i> , March 30, 2002, pp. 838-842, Vol. 77, No. 7.	
	R10	FURUKAWA, K. et al. "Effect of Culture Temperature on a Recombinant CHO Cell Line Producing a C-Terminal α-amidating Enzyme", <i>Cytotechnology</i> , 1998, pp. 153-164, Vol. 26.	
	R11	FURUKAWA, K. et al. "Enhancement of Productivity of Recombinant α-amidating Enzyme by Low Temperature Culture", <i>Cytotechnology</i> , 1999, pp. 85-94, Vol. 31.	
	R12	GAWLITZEK, M. et al. "Ammonium Alters N-Glycan Structures of Recombinant TNFR-IgG: Degradative Versus Biosynthetic Mechanisms", <i>Biotechnology and Bioengineering</i> , June 20, 2000, pp. 637-646, Vol. 68, No. 6.	

Examiner Signature	Date Considered

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Sheet

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First Named Inventor	Yolande Rouiller
Group Art Unit	
Examiner Name	

Attorney Docket Number ARS-129

**NON PATENT LITERATURE DOCUMENTS**

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	R13	GOLDMAN, M.H. et al. "Monitoring Proteolysis of Recombinant Human Interferon-γ During Batch Culture of Chinese Hamster Ovary Cells", <i>Cytotechnology</i> , 1997, pp. 103-111, Vol. 23.	
	R14	GRANTHAM, R. "Amino Acid Difference Formula to Help Explain Protein Evolution", <i>Science</i> , September 6, 1974, pp. 862-864, Vol. 185.	
	R15	HARVEY, D.J. "Matrix-assisted Laser Desorption/Ionisation Mass Spectrometry of Oligosaccharides and Glycoconjugates", <i>Journal of Chromatography A</i> , 1996, pp. 429-446, Vol. 720.	
	R16	HENDRICK, V. et al. "Increased Productivity of Recombinant Tissular Plasminogen Activator (t-PA) by Butyrate and Shift of Temperature: a Cell Cycle Phases Analysis", <i>Cytotechnology</i> , 2001, pp. 71-83, Vol. 36.	
	R17	HIRSCHBERG, C.B. et al. "Topography of Glycosylation in the Rough Endoplasmic Reticulum and Golgi Apparatus", <i>Ann. Rev. Biochem.</i> , 1987, pp. 63-87, Vol. 56.	
	R18	JENKINS, N. et al. "Getting the Glycosylation Right: Implications for the Biotechnology Industry", <i>Nature Biotechnology</i> , August 1996, pp. 975-981, Vol. 14.	
	R19	KAUFMANN, H. et al. "Influence of Low Temperature on Productivity, Proteome and Protein Phosphorylation of CHO Cells", <i>Biotechnology and Bioengineering</i> , June 5, 1999, pp. 573-582, Vol. 63, No. 5.	
	R20	KAUFMANN, H. et al. "Comparative Analysis of Two Controlled Proliferation Strategies Regarding Product Quality, Influence on Tetracycline-Regulated Gene Expression, and Productivity", <i>Biotechnology and Bioengineering</i> , March 20, 2001, pp. 592-602, Vol. 72, No. 6.	
	R21	LOETSCHER, H. et al. "Molecular Cloning and Expression of the Human 55 kd Tumor Necrosis Factor Receptor", <i>Cell</i> , April 20, 1990, pp. 351-359, Vol. 161, No. 2.	
	R22	MOORE, A. et al. "Effects of Temperature Shift on Cell Cycle, Apoptosis and Nucleotide Pools in CHO Cell Batch Cultures", <i>Cytotechnology</i> , 1997, pp. 47-54, Vol. 23.	
	R23	MUELLER, P.P. et al. "Recombinant Glycoprotein Product Quality in Proliferation-Controlled BHK-21 Cells", <i>Biotechnology and Bioengineering</i> , December 5, 1999, pp. 529-536, Vol. 65, No. 5.	
	R24	MUNZERT, E. et al. "Sialidase Activity in Culture Fluid of Chinese Hamster Ovary Cells during Batch Culture and Its Effect on Recombinant Human Antithrombin III Integrity", <i>Biotechnol. Prog.</i> , 1996, pp. 559-563, Vol. 12.	

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	R25	NOPHAR, Y. et al. "Soluble Forms of Tumor Necrosis Factor Receptors (TNF-Rs). The cDNA for the Type I TNF-R, Cloned Using Amino Acid Sequence Data of its Soluble Form, Encodes Both the Cell Surface and a Soluble Form of the Receptor", <i>The EMBO Journal</i> , 1990, pp. 3269-3278, Vol. 9., No. 10.	
	R26	NYBERG, G.B. et al. "Metabolic Effects on Recombinant Interferon-γ Glycosylation in Continuous Culture of Chinese Hamster Ovary Cells", <i>Biotechnology and Bioengineering</i> , February 5, 1999, pp. 336-347, Vol. 62, No. 3.	
	R27	PEARSON, W.R. et al. "Improved Tools for Biological Sequence Comparison", <i>Proc. Natl. Acad. Sci. USA</i> , April 1988, pp. 2444-2448, Vol. 85.	
	R28	PEARSON, W.R. et al. "Rapid and Sensitive Sequence Comparison with FASTP and FASTA", <i>Methods in Enzymology</i> , 1990, pp. 63-98, Vol. 183.	
	R29	SCHALL, T.J. et al. "Molecular Cloning and Expression of a Receptor for Human Tumor Necrosis Factor", <i>Cell</i> , April 20, 1990, pp. 361-370, Vol. 61.	
	R30	SMITH, C.A. et al. "A Receptor for Tumor Necrosis Factor Defines an Unusual Family of Cellular and Viral Proteins", <i>Science</i> , May 25, 1990, pp. 1019-1023, Vol. 248.	
	R31	SMITH, T.F. et al. "Identification of Common Molecular Subsequences", <i>J. Mol. Biol.</i> , 1981, pp. 195-197, Vol. 147.	
	R32	SURESHKUMAR, G.K. et al. "The Influence of Temperature on a Mouse-Mouse Hybridoma Growth and Monoclonal Antibody Production", <i>Biotechnology and Bioengineering</i> , February 1991, pp. 292-295, Vol. 37.	
	R33	WEIDERMANN, R. et al. "Low Temperature Cultivation- A Step Towards Process Optimisation", <i>Cytotechnology</i> , 1994, pp. 111-116, Vol. 15.	
	R34	WERNER, R. G. et al. "Appropriate Mammalian Expression Systems for Biopharmaceuticals", <i>Drug Res.</i> , 1998, pp. 870-880, Vol. 48, No. 8.	
	R35	YANG, M. et al. "Effects of Ammonia on CHO Cell Growth, Erythropoietin Production, and Glycosylation", <i>Biotechnology and Bioengineering</i> , May 20, 2000, pp. 370-380, Vol. 68, No. 4.	
	R36	YOON, S.K. et al. "Effect of Low Culture Temperature on Specific Productivity, Transcription Level, and Heterogeneity of Erythropoietin in Chinese Hamster Ovary Cells", <i>Biotechnology and Bioengineering</i> , May 5, 2003, pp. 289-298, Vol. 82, No. 3.	

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